PRIA Fee Category Table – Biopesticides Division – SCLP

Table 15.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote1"][1]	FY'17 & FY'18 Registration Service Fee ($)
[HYPERLINK "http://www2.epa.gov/pria-fees/b690-pria-fee-category"]	142	New active ingredient; food or non-food use. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote2"][6]	7	2,554
[HYPERLINK "http://www2.epa.gov/pria-fees/b700-pria-fee-category"]	143	Experimental Use Permit application; new active ingredient or new use.[6]	7	1,278
[HYPERLINK "http://www2.epa.gov/pria-fees/b701-pria-fee-category"]	144	Extend or amend Experimental Use Permit.[6]	4	1,278
[HYPERLINK "http://www2.epa.gov/pria-fees/b710-pria-fee-category"]	145	New product; registered source of active ingredient(s); identical or substantially similar in composition and use to a registered product; no change in an established tolerance or tolerance exemption. No data review, or only product chemistry data; cite-all data citation, or selective data citation where	4	1,278

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		applicant owns all required data or authorization from data owner is demonstrated. Category includes 100% re-package of registered end-use or manufacturing-use product that requires no data submission or data matrix. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote3"][6]		
[HYPERLINK "http://www2.epa.gov/pria-fees/b720-pria-fee-category"]	146	New product; registered source of active ingredient(s); requires: 1) submission of product specific data; or 2) citation of previously reviewed and accepted data; or 3) submission or citation of data generated at government expense; or 4) submission or citation of a scientifically-sound rationale based on publicly available literature or other relevant information that addresses the data requirement; or 5) submission of a	5	1,278

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		request for a data requirement to be waived supported by a scientifically-sound rationale explaining why the data requirement does not apply. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote3"](6)		
[HYPERLINK "http://www2.epa.gov/pria-fees/b721-pria-fee-category"]	147	New product; unregistered source of active ingredient. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote3"](6)	7	2,676
[HYPERLINK "http://www2.epa.gov/pria-fees/b722-pria-fee-category"]	148	New use and/or amendment; petition to establish a tolerance or tolerance exemption. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote4"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote5"](6)	7	2,477

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote1"][1]	FY'17 & FY'18 Registration Service Fee ($)
[HYPERLINK "http://www2.epa.gov/pria-fees/b730-pria-fee-category"]	149	Label amendment requiring data submission. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-biopesticides-division-sclp" \l "footnote4"][6]	5	1,278

[1]A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

[2]All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use.

Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

[3]An application for a new end-use product using a source of active ingredient that (a) is not yet registered but (b) has an application pending with the Agency for review, will be considered an application for a new product with an unregistered source of active ingredient.

[4](a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

[5]Amendment applications to add the new use(s) to registered product labels are covered by the base fee for the new use(s). All items in the covered application must be submitted together in one package. Each application for an additional new product registration and new inert approval(s) that is submitted in the new use application package is subject to the registration service fee for a new product or a new inert approval. However, if a new use application only proposes to register the new use for a new product and there are no amendments in the application, then review of one new product application is covered by the new use fee. All such associated applications that are submitted together will be subject to the new use decision review time. Any application for a new product or an amendment to the proposed labeling (a) submitted subsequent to submission of the new use application and (b) prior to conclusion of its decision review time and (c) containing the same new uses, will be deemed a separate new-use application, subject to a separate registration service fee and new decision review time for a new use. If the new-use application includes non-food (indoor and/or outdoor), and food (outdoor and/or indoor) uses, the appropriate fee is due for each type of new use and the longest decision review time applies to all of the new uses requested in the application. Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screen, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new use application.

[6]Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of

the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.